Claims

- 1. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of highly-compactable filler in combination with a highly water-absorbing material and;
 - b) adding purified water to the mixture of highly compactable filler and highly water-absorbing material until granules are formed by visual inspection thus creating the cushioning component; and
 - c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and
 - d) adding active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
 - e) freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization to create the Cushioning BeadsTM; and
 - f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 2. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of Avicel® PH101 and Ac-Di-Sol® and;
 - b) adding purified water to the mixture of Avicel® PH101 and Ac-Di-Sol® until granules are formed by visual inspection thus creating the cushioning component and;
 - the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and
 - d) adding of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and

- e) freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization to create the Cushioning BeadsTM; and
- f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 3. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of Avicel® PH101 and Ac-Di-Sol® in a ratio that the mixture will have Ac-Di-Sol ranging from 5 to 90% by weight and;
 - b) adding of purified water to the mixture of Avicel® PH101 and Ac-Di-Sol® until granules are formed by visual inspection thus creating the cushioning component and;
 - c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and
 - d) adding of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
 - e) freeze-drying of the mixture of active-loaded beads and the milled cushioning component with or without said extrusion and spheronization to create the Cushioning BeadsTM; and
 - f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 4. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of a highly-compactable filler in combination with a highly water-absorbing material and;
 - b) adding of purified water to the mixture of highly-compactable filler and highly water-absorbing material until granules are formed by visual inspection thus creating the cushioning component and;
 - c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 45 micron); and

d) adding of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including nonactive ingredients to improve patient compliance, functionality or manufacturability; and

- e) freeze-drying of the mixture of active-loaded beads and the milled cushioning component with or without said extrusion and spheronization until a LOD of 2-15% is achieved to create the Cushioning BeadsTM followed by an optional step of extrusion and spheronization of the Cushioning BeadsTM; and
- f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 5. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of Avicel® PH101 and Ac-Di-Sol® and;
 - b) adding purified water to the mixture of Avicel® PH101 and Ac-Di-Sol® until granules are formed by visual inspection thus creating the cushioning component and;
 - c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and
 - d) adding of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
 - e) freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization until a LOD of 2-15% is achieved to create the Cushioning BeadsTM; and
 - f) compressing the Cushioning BeadsTM into a fast tablet for treatment of a patient in need of said treatment.
- 6. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of Avicel® PH101 and Ac-Di-Sol® in a ratio that the mixture will have Ac-Di-Sol ranging from 5 to 90% by weight;

- b) adding of purified water to the mixture of Avicel® PH101 and Ac-Di-Sol® until granules are formed by visual inspection thus creating the cushioning component and;
- c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and
- d) adding of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
- e) freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization until a LOD of 2-15% is achieved to create the Cushioning BeadsTM; and
- f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 7. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of a highly-compactable filler in combination with a highly water-absorbing material and;
 - b) adding purified water to the mixture of highly-compactable filler and highly water-absorbing material until granules are formed by visual inspection thus creating the cushioning component and;
 - c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and
 - d) adding more than one type of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
 - e) freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization to create the Cushioning BeadsTM; and

- f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 8. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of Avicel® PH101 and Ac-Di-Sol® and;
 - b) adding purified water to the mixture of Avicel® PH101 and Ac-Di-Sol® until granules are formed by visual inspection thus creating the cushioning component and;
 - c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 45 micron); and
 - d) adding of more than one type of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
 - e) freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization to create the Cushioning BeadsTM; and
 - f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 9. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of Avicel® PH101 and Ac-Di-Sol® in a ratio that the mixture will have Ac-Di-Sol ranging from 5 to 90% by weight and;
 - b) adding of purified water to the mixture of Avicel® PH101 and Ac-Di-Sol® until granules are formed by visual inspection thus creating the cushioning component and;
 - c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and
 - d) adding of more than one type of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive

- ingredients to improve patient compliance, functionality or manufacturability; and
- e) freeze-drying of the mixture of active-loaded beads and the milled cushioning component with or without said extrusion and spheronization to create the Cushioning BeadsTM; and
- f) compressing the Cushioning Beads[™] into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 10. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of a highly-compactable filler in combination with a highly water-absorbing material and;
 - b) adding of purified water to the mixture of highly-compactable filler and highly water-absorbing material until granules are formed by visual inspection thus creating the cushioning component and;
 - c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and
 - d) adding of more than one type of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
 - e) freeze-drying of the mixture of active-loaded beads and the milled cushioning component with or without said extrusion and spheronization until a LOD of 2-15% is achieved to create the Cushioning BeadsTM; and
 - f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 11. A method for the of manufacture of a fast dissolve tablet that includes:
 - a) blending of Avicel® PH101 and Ac-Di-Sol® and;
 - b) adding purified water to the mixture of Avicel® PH101 and Ac-Di-Sol® until granules are formed by visual inspection thus creating the cushioning component and;

c) the cushioning component is milled to a particle size of between 10-325 mesh (2000 – 45 micron); and

- d) adding of more than one type of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
- e) freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization until a LOD of 2-15% is achieved to create the Cushioning BeadsTM; and
- f) and compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.
- 12. A method for the manufacture of a fast dissolve tablet that includes:
 - a) blending of Avicel® PH101 and Ac-Di-Sol® in a ratio that the mixture will have Ac-Di-Sol ranging from 5 to 90% by weight and;
 - b) adding of purified water to the mixture of Avicel® PH101 and Ac-Di-Sol® until granules are formed by visual inspection thus creating the cushioning component and;
 - the cushioning component is milled to a particle size of between 10 mesh (2000 45 micron); and
 - d) adding of more than one type of active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and the option of including inactive ingredients to improve patient compliance, functionality or manufacturability; and
 - e) freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization until a LOD of 2-15% is achieved to create the Cushioning BeadsTM; and

f) compressing the Cushioning BeadsTM into a fast dissolve tablet for treatment of a patient in need of said treatment.